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IS 8810 (1985): Rongine for Lacrimal SAC, Rollet's Pattern
(Modified) [MHD 5: Ophthalmic Instruments and Appliances]

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Indian Standard
SPECIFICATION FOR
ROUGINE FOR LACRIMAL SAC,
ROLLET'S PATTERN (MODIFIED)
(*First Revision*)

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Indian Standard

SPECIFICATION FOR
ROUGINE FOR LACRIMAL SAC,
ROLLET'S PATTERN (MODIFIED)

(First Revision)

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Indian Standard

SPECIFICATION FOR

ROUGINE FOR LACRIMAL SAC,

ROLLET'S PATTERN (MODIFIED)

(First Revision)

0. F O R E W O R D

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 25 November 1985, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard was first published in 1978. The present revision has been taken up to include certain modifications in order to bring the specification in line with the modern manufacturing practices. In the revised standard the non-functional dimensions have been rounded off. The tolerance for the functional dimensions have been modified keeping in view the present manufacturing technique. A clause on sampling and inspection has been added. The test methods have been brought in line with the test methods covered in other similar standards of eye surgery instruments.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

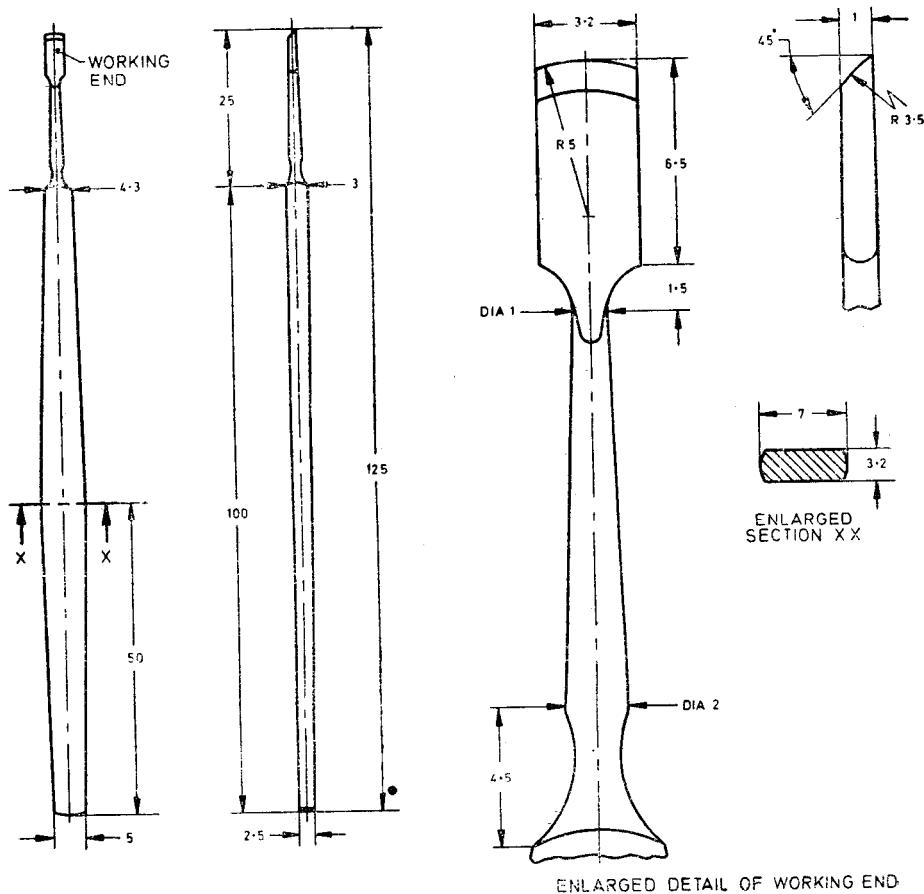
1. SCOPE

1.1 This standard covers requirements for Rollet's pattern rougine for lacrimal sac used in eye surgery.

2. SHAPE AND DIMENSIONS

2.1 The shape and dimensions shall be as shown in Fig. 1.

*Rules for rounding off numerical values (revised).



All dimensions in millimetres.

FIG. 1 ROUGINE FOR LACRIMAL SAC, ROLLET'S PATTERN (MODIFIED)

2.2 A deviation of ± 2.5 percent shall be allowed on all dimensions.

3. MATERIAL

3.1 The material for rougine shall be stainless steel conforming to Designation 30Cr13 of IS : 6603-1972*.

*Specification for stainless steel bars and flats.

4. REQUIREMENTS

- 4.1** The rougine shall be free from burrs, pits, cracks and other surface defects.
- 4.2** The rougine shall be made in one piece.
- 4.3** The rougine shall have smooth sharp cutting edge.
- 4.4** The cutting edge shall not have any feather and nick.
- 4.5** The rougine shall be passivated and polished bright.
- 4.6** The handle shall have smooth finish.

5. HARDNESS

- 5.1** The rougine shall be uniformly hardened and tempered to give a hardness of 400 to 460 HV.

6. TESTS

- 6.1 Corrosion Resistance Test** — The rougine shall be tested in accordance with the method covered in IS : 7531-1975*. The rougine shall not show any sign of corrosion after the test.

- 6.2 Performance Test** — A piece of soft wood shall be scraped 12 times to and fro with the rougine. The rougine shall cleanly scrape the wood and shall not get damaged or blunt after the test.

7. SAMPLING AND CRITERIA FOR CONFORMITY

- 7.1** A suitable sampling scheme and criteria for acceptance is given in Appendix A.

8. MARKING

- 8.1** Each rougine shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark and the word 'stainless steel' or letters 'SS'.

- 8.1.1** The rougine may also be marked with ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

*Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments.

9. PACKING

9.1 The rougine shall be packed individually in such a way that they do not move inside the carton in transit and the working end does not get damaged or as agreed to between the purchaser and the supplier.

A P P E N D I X A

(Clause 7.1)

SAMPLING AND CRITERIA FOR CONFORMITY FOR ROUGINE

A-1. Lot — In any consignment, all the rougines produced from the same material and same shape and dimensions under similar conditions, shall constitute a lot.

A-2. The number of rougines to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

LOT SIZE (1)	SAMPLE SIZE (2)
Up to 15	2
16 ,, 50	3
51 ,, 150	5
151 and above	8

A-2.1 These rougines shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905-1968* may be followed.

A-3. Number of Tests and Criteria for Conformity — All the rougines selected at random in accordance with col 1 and 2 of Table 1 shall be tested for hardness, corrosion resistance test, and performance test. The lot shall be considered as conforming to these requirements if none of the rougines in the sample is found to be defective in any of these tests.

*Methods for random sampling.